



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

FILE COPY

April 5, 2005

Joseph W. Allen
Jaeckle Fleischmann & Mugel, LLP
12 Fountain Plaza
Buffalo, New York 14202-2292

Dear Mr. Allen:

Your advisory opinion request to the Food and Drug Administration, submitted on behalf of Great Lakes Orthodontics, Ltd., concerning a 510(k) for a medical or dental device, was received by this office on 04/05/2005. It was assigned docket number 2005A-0131/AP1 and it was filed on 04/05/2005. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Gloria Ortega
Division of Dockets Management
Office of Management Programs
Office of Management

2005A-0131

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